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**IS : 11661 - 1986**

# *Indian Standard*

# SPECIFICATION FOR SAFETY OF LUNG VENTILATOR FOR MEDICAL USE

UDC 615·841 : 614·894·2 [ 616·24 ]

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

**Gr 3** *March* 1987

# AMENDMENT NO. 1 MAY 2007
# TO
# IS 11661 : 1986 SPECIFICATION FOR SAFETY OF LUNG VENTILATOR FOR MEDICAL USE

(*Page* 3, *clause* **2.0**) Substitute 'IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988 Medical electrical equipment : Part 1 General requirements for safety' *for* 'IS : 8607 (Part 1) - 1977†' alongwith its footnote.

(*Page* 3, *clause* **3.2**) -- Substitute 'IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 1) - 1977†' alongwith its footnote.

(*Page* 3, *clause* **4.1**) — Substitute '*clause* 6 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 1) - 1977†' alongwith its footnote.

(*Page* 4, *clause* **5.1**) -- Substitute '*clause* 4 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* '5 of IS : 8607 (Part 1) - 1977*' alongwith its footnote.

(*Page* 6, *clause* **10.1**) — Substitute '*clause* 3.6 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 1) - 1977*' alongwith its footnote.

(*Page* 7, *clause* **11.1**) — Substitute 'Section 3 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 2) - 1978*' alongwith its footnote.

(*Page* 7, *clause* **12.1**) — Substitute 'Section 4 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 3) - 1979†' alongwith its footnote.

(*Page* 7, *clause* **13.1**) — Substitute 'Section 5 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 4) - 1985‡' alongwith its footnote.

(*Page* 7, *clause* **14.1**) — Substitute 'Section 6 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 5) - 1983§' alongwith its footnote.

(*Page* 7, *clause* **15.1**) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984 ' alongwith its footnote.

[*Page* 8, *clause* 15.2(i), (ii) & (iii)] — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 8, *clause* 15.3) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 8, *clause* 15.3.1) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 8, *clause* 15.3.2, *first and second line*) — Substitute 'Section 6 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 5) - 1983†' alongwith its footnote.

(*Page* 8, *clause* 15.3.2, *fourth line*) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 8, *clause* 15.4) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 9, *clause* 15.6) — Substitute 'Section 7 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 6) - 1984*' alongwith its footnote.

(*Page* 10, *clause* 17.1) — Substitute 'Section 10 of IS 13450 (Part 1) : 1994/IEC Pub 601-1 : 1988' *for* 'IS : 8607 (Part 7) - 1985*' alongwith its footnote.

(MHD 15)

Reprography Unit, BIS, New Delhi, India

# *Indian Standard*

# SPECIFICATION FOR SAFETY OF LUNG VENTILATOR FOR MEDICAL USE

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# *Indian Standard*

# SPECIFICATION FOR SAFETY OF LUNG VENTILATOR FOR MEDICAL USE

## 0. FOREWORD

**0.1** This Indian Standard was adopted by the Indian Standards Institution on 16 April 1986, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

**0.2** The purpose of this standard is to establish minimum requirements for the safety of lung ventilators with particular reference to safety against electric shock hazard and prevention of fires in oxygen enriched atmosphere materials which do not ignite in air but may ignite and burn violently in oxygen. It is, therefore, essential to take all precautionary measures in the use of lung ventilator for medical use. The minimum safety requirements as specified in this standard are considered to provide for an acceptable level of safety in operation and reliability in use.

**0.3** In the preparation of this standard, assistance has been derived from IEC document 62D ( Central Office ) 36 Medical electrical equipment — Part 2 Particular requirements for the safety of lung ventilators for medical use, issued by the International Electrotechnical Commission ( IEC ).

**0.4** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## 1. SCOPE

**1.1** This standard specifies the safety requirements for lung ventilator incorporating electric devices, designed for medical use with adult, pediatric or neonatal patients.

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*Rules for rounding off numerical values ( *revised* ).

1.2 This standard does not apply to lung ventilators for use with animals.

## 2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions in addition to those given in IS : 1885 ( Part 43 )-1977* and IS : 8607 ( Part 1 )-1977† shall apply.

2.1 **Breathing Systems** — The gas pathway in direct connection with the patient through which intermittent or reciprocating gas flow occurs and into which a mixture of controlled composition may be dispensed.

2.2 **Lung Ventilator** – An automatic device, which is connected to the patient's airway and is designed to augment ventilation or provide ventilation for the patient.

2.3 **Applied Part** — For the purpose of this standard the applied part is the machine outlet(s) and other parts of the lung ventilator which are intended to be connected with the patient or with the breathing system.

2.4 **Machine Outlets** — For the purpose of this standard, the machine outlets is that part(s) through which gases pass into or from the breathing system of a lung ventilator.

## 3. GENERAL REQUIREMENTS

3.1 Equipment shall be so designed, constructed and manufactured that, when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, it causes no danger which could reasonably be foreseen other than that connected with its intended application for diagnostic or therapeutic purposes, to the user, to the patient or to the surroundings in normal use and in single fault condition.

3.2 The lung ventilator shall satisfy the general safety requirements as given in IS : 8607 ( Part 1 )-1977‡.

## 4. IDENTIFICATION, MARKING AND ACCOMPANYING DOCUMENTS

4.1 The relevant requirements of IS : 8607 ( Part 1 )-1977† shall apply.

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*Electrotechnical vocabulary: Part 43 Electrical equipment used in medical practice.

†General and safety requirements for electrical equipment used in medical practice: Part 1 General.

**4.2 Accompanying Documents** — In addition to the information of accompanying documents as required in this standard, the instructions for use shall include the following additional statements:

a) A warning to the effect that this lung ventilator shall not be used with flammable anaesthetic agents, and

b) A statement to the effect that antistatic or electrically conductive hoses or tubings should not be used.

NOTE — The use of antistatic or electrically conductive materials or both in the breathing system of lung ventilators is not considered as contributing to any higher degree of safety. On the contrary, the use of such materials increases the hazard of electrical shock to the patient and oxygen fire.

**4.3** If the equipment has an internal electrical power source, the instructions for use shall include a specification of the operating time under conditions specified by the manufacturer.

NOTE — The operating time may vary considerably and be affected by temperature in both charging and discharging rate of the battery.

**4.4** Unless it can be demonstrated that the equipment is not susceptible to electromagnetic interference, the instructions for use shall include a warning statement to the effect:

> 'The functioning of this machine may be adversely affected by the operation of equipment such as high-frequency surgical apparatus or short-wave therapy equipment in the vicinity'.

## 5. GENERAL REQUIREMENTS FOR TEST

**5.1** Relevant requirements of 5 of IS : 8607 ( Part 1 )-1977* shall apply.

## 6. POWER INPUT

**6.1** The steady state current and the power consumption of equipment, at rated voltage, steady state operating temperature and at operational settings specified by the manufacturer, shall not exceed the marked rating by more than the values specified below:

a) For equipment with power consumption mainly caused by electric motor drive(s):

   i) +25 percent for a rated input power up to and including 100 W or 100 VA, and

   ii) +15 percent for a rated input power over 100 W or 100 VA.

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*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

b) For all equipment other than that specified under (a):

   i) + 15 percent for a rated input power up to and including 100 W or 100 VA, and

   ii) + 10 percent for a rated input power over 100 W or 100 VA.

**6.2** The current or power consumption in cold conditions may deviate from the marked rating but shall not be more than 120 percent of the marked rating unless a greater deviation is allowed according to **6.1**.

**6.3** Compliance with the requirements of **6.1** and **6.2** shall be checked by the tests given in **6.3.1**.

**6.3.1** The equipment shall be operated as specified in the instructions for use until the input has reached a stable value. The current or power consumption shall be measured and compared with the markings or the contents of the accompanying documents. The measured values shall not exceed the limits specified in **6.1**.

For equipment marked with one or more rated voltage ranges, the test is made at both the upper and lower limits of the ranges except the equipment marked with the voltage range, in which case the test is made at a voltage equal to the mean value of that range. The steady state current shall be measured with a true root mean square (rms) reading instrument such as a thermal instrument.

## 7. REMOVABLE PROTECTIVE MEANS

**7.1** If the equipment has alternative applications which require the removal of a protective means to utilize a particular function, the protective means shall be marked to indicate the necessity for replacement when access to the function is no longer needed. The instructions for use shall also carry a similar notice.

Protective means should be incorporated as far as possible in the basic design of the equipment.

**7.2** However, this requirement applies only for alternative application specified by the manufacturer.

## 8. SPECIAL ENVIRONMENTAL CONDITIONS

**8.1** Where equipment has been specified by the manufacturer for use in environmental or operational conditions differing from those indicated in this standard, additional safety measures may have to be applied. However, the basic requirements of this standard shall always be fulfilled within the environmental and operational conditions specified by the manufacturer.

Special conditions may prevail, in the following cases:

i) In environments with an explosion hazard;

ii) At unusual high or low temperatures;

iii) At abnormal humidity;

iv) At unusual chemical or physical stresses;

v) In oxygen-enriched environments; and

vi) At atmospheric air pressure exceeding the limits of the scope of this standard.

## 9. SPECIAL MEASURES WITH RESPECT TO SAFETY

**9.1** Equipment may be exempted from some safety requirements of this standard if special safety measures are applied which are independent of the nature and function of the equipment, for example:

i) For use in locations with restricted access; and

ii) For restricted use of a limited category of persons familiar with the special hazards associated with the proper use of the equipment and with necessary or suitable measures which can be applied to avoid or restrict these hazards ( for example, in laboratories, testing stations, etc ).

In such cases, the equipment shall be marked to indicate the safety features which are absent.

## 10. SINGLE FAULT CONDITIONS

**10.1** Requirements specified in **9.5** of IS : 8607 ( Part 1 )-1977* shall apply except that such single fault conditions due to short and open circuits of components or wiring are applicable.

**10.2** Applicable single fault conditions are short and open circuits of components or wiring, which:

a) cause sparks to occur, or

b) increase the energy of sparks, or

c) increase temperatures.

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*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

## 11. PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

**11.1** The provisions of IS : 8607 ( Part 2 )-1978* shall apply.

**11.1.1** However deterioration of parts due to oxygen and anaesthetic agents shall be taken into account while considering the requirements for insulation and protective impedance.

**11.1.2** *Measurement of Patient Leakage Current* — The patient leakage current shall be measured from the machine outlet(s) and other parts which are defined as applied parts for the purpose of this standard. All these parts shall be connected together electrically with the exception of parts connected to the protective earth terminal which shall be tested separately from parts not so connected.

## 12. PROTECTION AGAINST MECHANICAL HAZARDS

**12.1** Provisions of IS : 8607 ( Part 3 )-1979† shall apply.

## 13. PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESS RADIATION

**13.1** Provisions of IS : 8607 ( Part 4 )-1985‡ shall apply.

## 14. PROTECTION AGAINST EXPLOSION HAZARDS

**14.1** Provisions of IS : 8607 ( Part 5 )-1983§ shall apply.

**14.2 Warning** — Oxygen flow shall be stopped before operating the defibrillators.

## 15. PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS

**15.1** Provisions of IS : 8607 ( Part 6 )-1984|| shall apply except as stated in **15.2**.

**15.2** In order to eliminate the risk of oxygen fire caused by electrical components which might be a source of ignition in enclosed compartments of equipment containing an oxygen system, at least one of the

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General and safety requirements for electrical equipment used in medical practice:

*Part 2 Protection against electric shock.

†Part 3 Protection against mechanical hazards.

‡Part 4 Protection against unwanted or excessive radiation.

§Part 5 Protection against explosion hazards.

||Part 6 Protection against excessive temperature, fire and other hazards.

following requirements shall be satisfied:

i) Electrical components shall be separated from compartments in which accumulations of such gases can occur by a barrier complying with the requirements of IS : 8607 ( Part 6 )-1984*.

ii) Compartments containing electrical components shall be ventilated according to the requirements of IS : 8607 ( Part 6 )-1984*.

iii) Electrical components which, in normal use or single fault conditions can be a source of ignition, shall comply with the requirements of IS : 8607 ( Part 6 )-1984*.

**15.3** Any barrier required under the provision of IS : 8607 ( Part 6 ) 1984* shall be sealed at all joints and at any holes for cables or for other purposes.

**15.3.1** Compliance shall be checked by inspection and if applicable by the compliance test described in IS : 8607 ( Part 6 )-1984* for enclosures with restricted breathing.

**15.3.2** The internal overpressure of 4 mbar specified in IS : 8607 (Part 5 )-1983† is not applicable when, in normal use, a pressure difference exists between the spaces separated by the barrier. In such a case, the compliance test of IS : 8607 ( Part 6 )-1984* applies.

**15.4** The ventilation required under the provisions of IS : 8607 ( Part 6 )-1984* shall be such that the oxygen content in the compartment containing electrical components shall not exceed 4 volume percent above the ambient level. If this requirement is met by forced ventilation, a ventilation failure alarm shall be provided.

**15.4.1** Compliance shall be checked by the following test:

The oxygen concentration shall be measured under the following conditions and for such a period that the highest possible concentration of oxygen occurs:

i) Single fault condition;

ii) The oxygen flow shall be equal to the sum of the maximum flows in normal use of oxygen and nitrous oxide;

iii) Selection of the least favourable control settings;

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General and safety requirements for electrical equipment used in medical practice:

*Part 6 Protection against excessive temperature fire and other hazards.

†Part 5 Protection against explosive hazards.

iv) Mains supply voltage deviations of ±10 percent;

v) The measurements shall be repeated after 18 h during which time the supply voltage shall have been switched off and the gas supply shall have remained on; and

vi) The rate of air exchange in the test room shall be between 3 and 10 per hour.

**15.5** Electrical circuits which can produce sparks or generate increased surface temperatures and which might otherwise be a source of ignition shall be so designed that in normal use and single fault condition no ignition occurs.

At least the following requirements shall be satisfied:

i) The product of the rms value of the no load voltage and the rms value of the short circuit current shall not exceed 10 VA.

ii) The surface temperature of components shall not exceed 300°C.

**15.5.1** Compliance shall be checked by the following test.

**15.5.1.1** Voltage and currents in steady state conditions shall be measured or calculated and surface temperatures shall be measured in normal use and single fault conditions.

**15.6** External exhaust gas outlets shall be located at least 20 cm from any electrical component mounted on the outside of the equipment which can spark in normal use or single fault condition.

Compliance shall be checked by inspection and/or measurement as given in IS : 8607 ( Part 6 )-1984*.

## 16. INTERRUPTION OF POWER SUPPLY

**16.1** Thermal cut-outs and overload protective devices with automatic resetting shall not be used if they may cause danger by such resetting.

**16.2** Equipment shall be so designed that an interruption and restoration of the power supply shall not result in a hazard other than interruption of its intended function.

**16.3** Means shall be provided for the removal of mechanial pressures on a patient in case of a failure of the supply mains.

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*General and safety requirements for electrical equipment used in medical practice: Part 6 Protection against excessive temperature, fire and other hazards.

**16.4** Mains operated life-supporting equipment should, as far as possible, be so designed that after a failure of the supply mains, vital functions are restored to operation when the supply mains is returned without any act from a user.

For example, no push-button actuated contactors with a latching circuit should be used, in the mains part.

**16.4.1** If automatic restoration is not possible or not wanted for safety reasons, an audible alarm to indicate failure of the supply mains should be provided. In the event of the interruption of the main power supply excluding the operation of mains off switch, the equipment shall immediately give an audible alarm for at least 120 s.

## 17. SAFETY PROVISIONS IN CONSTRUCTION

**17.1** Relevant provisions of IS : 8607 ( Part 7 )-1985* shall apply except that the mains supply chord of electrical lung ventilator shall be preferably a non-detachable chord or shall be protected against accidental disconnection.

**17.2** The detachable chord is subjected for 1 min to an axial pull of force given below:

| *Mass of Equipment* (kg) | *Pull* (N) |
|---|---|
| Up to and including 1 | 30 |
| Over 1 up to and including 4 | 60 |
| Over 4 | 100 |

During the test, the mains connector shall not become disconnected from the appliance inlet.

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*General and safety requirements for electrical equipment used in medical practice: Part 7 Construction.

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Printed at Arcee Press, New Delhi, India